DEPARTMENT OF THE ARMY
U.S. ARMY CONTRACTING COMMAND – NEW JERSEY
PICATINNY ARSENAL, NEW JERSEY 07806-5000

REPLY TO
ATTENTION OF

21 December 2020

Army Contracting Command – New Jersey
ACC-NJ, Building 9
Picatinny Arsenal, NJ 07806

SUBJECT: Technical Direction Letter for Medical CRBN Defense Consortium (MCDC), Request for Prototype Proposals (RPP) 20-11, Objective PRE-20-11 for Definitized "Rapid (WF10) Advanced Research & Development to Large Scale Manufacturing of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus" (Novavax, Inc.)

Advanced Technology International
ATTN: (b) (6)
315 Sigma Drive
Summerville, SC 29486

Dear (b) (6),

The Army Contracting Command – New Jersey (ACC-NJ), in supporting the Joint Project Manager – Medical Countermeasure Systems (JPM-MCS), issued MCDC RPP 20-11 on 09 June 2020. Members of the MCDC submitted proposals in accordance with this RPP. The Government received and evaluated all proposal(s) submitted and a Basis of Selection has been executed, selecting Novavax as the awardee. The Government requests that a Cost-Plus-Fixed-Fee Project Agreement be issued to Novavax to award this proposal under Other Transaction Agreement W15QKN-16-9-1002, to be performed in accordance with the attached Government Statement of Work (SOW).

The Government received the undefinitized Rough Order of Magnitude (ROM) proposal update on 02 July 2020, and reviewed the costs and documentation accordingly. Based on the acceptable ROM proposal update, the Government issued an Undefinitized Project Action (UPA) on 06 July 2020. In order to definitize the UPA, the Government finalized an analysis of the cost proposal on 10 December 2020, which focused on evaluation of the cost components and documentation. Based upon the acceptable update of Novavax's proposal for "Rapid (WF10) Advanced Research & Development to Large Scale Manufacturing of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus" and 1) The Project Agreement Recipient's concurrence with the requirements included in the Government SOW; 2) An acceptable milestone schedule that meets SOW requirements, and; 3) The ROM that has been analyzed and concurred to by the Government, you are hereby directed to issue a Definitized Project Agreement to Novavax for the subject project. The total project value has been determined fair and reasonable, and the ceiling will be updated in a future prime modification. See below for the ceiling adjustment.

	MCDC2011-001 Current Ceiling	MCDC2011-001 Proposed Increase	MCDC2011-001 Revised Ceiling
Member Ceiling	$1,600,434,522.00	$147,254,806.00	$1,747,689,328.00

ATI non G&A Costs	$60,000.00	$0.00	$60,000.00
ATI G&A Special Allocation	$225,000.00	$0.00	$225,000.00
Total	$1,600,719,522.00	$147,254,806.00	$1,747,974,328.00

The total approved cost to the Government for this effort is not to exceed $1,747,974,328.00. The break-out of the costs is as follows: $1,747,689,328.00 to perform project efforts included in the SOW and $285,000.00 for the Consortium Management Firm (CMF) Administrative Cost. The CMF Administrative Cost was approved as a "Special Allocation" for Operation Warp Speed (OWS) Prototype Projects executed under the MCDC OTA. The effort currently has $1,600,534,523.00 of available funding, comprised of $1,600,339,523.00 for the Project Agreement and $285,000.00 for the CMF Special Allocation. In alignment with the special allocation conditions, it is noted that this project has a base period of performance of eighteen (18) months.

This Project Agreement is anticipated to be incrementally funded. The Government reserves the right to award future milestones/fund additional months of project tasks. If the Government decides to do so, the MCDC member will be notified via ATI. The Government's liability will never exceed the current amount of funding obligated under the Project Agreement. The Project Agreement Holder shall notify ATI when they are approaching 75% of current funding obligated in incurred costs by written notice.

The prime contractor is considered a small business, nontraditional defense contractor, or nonprofit research institution and determined to be providing a significant contribution. The affirmation of business status certifications submitted as part of the proposal are hereby incorporated into the agreement. The contractor shall notify the MCDC CMF of any deviation from the final proposed affirmation of business status certifications that would affect the contributions of the small business, nontraditional defense contractor, or nonprofit research institution as proposed.

In accordance with 10.U.S.C. 2371b(f), and upon a determination that the prototype project for this transaction has been successfully completed, this competitively awarded prototype OTA may result in the award of a follow-on production contract or transaction without the use of competitive procedures.

In addition, ATI is advised of the implementation guidance for Section § 889(a)(1)(B) of the John S. McCain National Defense Authorization Act (NDAA) for Fiscal Year 2019 (Pub. L. 115–232), which prohibits executive agencies from entering into, extending, or renewing a contract with an entity that uses any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. While the interim rule and Defense Pricing and Contracting (DPC) implementation memorandum are directed to FAR-based contracts, the § 889(a)(1)(B) prohibition went into effect August 13, 2020, and applies to Other Transactions (OTs) for Prototype Projects under § 2371b of title 10, United States Code (U.S.C.). Any OT for Prototype Project agreement on or after August 13, 2020 must contain an article for the Prohibition on the Use of Certain Telecommunications and Video Surveillance Services or Equipment that requires the offeror to represent if it uses any equipment, system, or service that uses covered telecommunications equipment or services.

ATI must receive § 889(a)(1)(B) Certification from the MCDC member prior to executing any new project agreements or modification to an existing project agreement. A copy of the certification shall be provided to the undersigned.

Points of Contact:

Agreements Specialist:
(b) (6)
E-mail: (b) (6)
Phone: (b) (6)

Agreements Officer:
(b) (6)
E-mail: (b) (6)
Phone: (b) (6)

Regards,

X (b) (6)

(b) (6)
Agreements Officer
Signed by: (b) (6)

Attachments:
Attachment 1: Attachment A_MCDC2011-001 SOW_M04_Definitization_8DEC2020

Attachment A
Statement of Work
(Incorporated as of Modification No. 04; changes to Sections 4, 5, and 11 are indicated in bold italics.)

For
Rapid (WF10) Advanced Research & Development to Large Scale Manufacturing of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus

RPP #: 20-11
Project Identifier: MCDC2011-001
Consortium Member: Novavax, Inc.
Title of Proposal: Rapid (WF10) Advanced Research & Development to Large Scale Manufacturing of NVX-CoV-2373 as a Vaccine for SARS-CoV-2 Coronavirus
Requiring Activity: Joint Mission between the Department of Health and Human Services and Department of Defense to Combat COVID-19

1.0 INTRODUCTION, SCOPE, AND OBJECTIVES

1.1 Introduction

To meet the needs of the Coronavirus Disease 2019 (COVID-19) pandemic, the United States Government (USG) is identifying and will support development and at-scale manufacturing of selected vaccine candidates, to ensure timely availability to the US population when needed. This is the primary focus of the mission being executed by the Department of Health and Human Services (HHS) and Department of Defense (DoD), in support of Operation Warp Speed (OWS).

The USG is interested in pursuing prototype vaccines that are in an advanced stage of development, and will support companies that can, in parallel with nonclinical, clinical and regulatory development, rapidly establish the manufacturing capacity required to meet the USG's objective of supplying a safe and effective Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) vaccine to the entire US population. The USG is tasked with marshaling the efforts of the US biotechnology industry to achieve this goal.

1.2 Definition of the Prototype Project

Consistent with USG objectives, the "prototype project" under this agreement is defined as the manufacture and delivery of 100M doses of a SARS-CoV-2 vaccine, NVX-CoV2373, which is suitable for use in humans under a sufficiently informed deployment strategy, and the advanced positioning of a stockpile of critical long lead raw materials for the Matrix-M adjuvant. As such, the "prototype project" will effectively demonstrate Novavax's ability to rapidly stand up large scale manufacturing and seamlessly transition into ongoing production.

The NVX-CoV-2373 vaccine is comprised of the Matrix-M™ adjuvant, and antigen (SARS-CoV-2 spike protein). The vaccine is filled into a multi-dose vial (b) (4)) and is stored at refrigerated temperature (2-8ºC).

Successful development of the prototype will demonstrate Novavax's ability to rapidly stand up large scale manufacturing and seamlessly transition into ongoing production capability, in order to rapidly manufacture to meet surge requirements with little advance notification, and demonstrate capability to stockpile and distribute large quantities of the vaccine to respond when needed, including in order to supply use in clinical studies, under an Emergency Use Authorization (EUA), or pursuant to other clearance from the U.S. Food and Drug Administration (FDA).

Successful completion of the prototype will require three coordinated and integrated lines of effort:

a) Large scale manufacturing, compliant with 21 CFR Parts 210 and 211, and the Drug Supply Chain Security Act (DSCA), to the extent applicable at the time of manufacturing by statute and FDA interpretive guidance thereof.
b) Parallel nonclinical and clinical studies required to determine if the vaccine is safe and effective.
c) Compliance with all applicable U.S. regulatory requirements.

It is important to note that while results of nonclinical and clinical studies are critical to develop use case scenarios and, in turn, inform the USG's deployment strategy as it relates to product manufactured under this agreement, successful development of the prototype is dependent only on the validity of data from these studies. The degree to which the data are "positive" or "negative" is not a factor in demonstration of the prototype.

1.3 Follow-on Activity

This prototype project includes unpriced options for follow-on production/procurement. During the performance of the prototype, the USG and Novavax will negotiate the scope and price of production/procurement. If the prototype project is successful, the USG may then enter into follow-on production/procurement by executing these options through a separate stand-alone production/procurement agreement, to be negotiated in terms of scope and price as described in the following paragraph.

In accordance with 10.U.S.C. 2371b(f), and upon demonstration of the prototype, or at the accomplishment of particularly favorable or unexpected results that would justify transitioning to production/procurement, EUA, or Biologics License Application (BLA) approved by the FDA, the USG and Novavax may enter into a non-competitive production/procurement follow-on agreement or contract for additional production/procurement, to partially or completely meet the USG objective of supplying a safe and effective SARS-CoV-2 vaccine to vaccinate up to 300M people in the targeted population (≈560M additional doses).

1.4 Scope

Novavax has defined a scope of activities in order to successfully develop the prototype, as defined above. The scope is based on the following assumptions regarding manufacturing and clinical dose:

- Manufacturing Assumptions and Clinical Dose
  - The NVX-CoV-2373 vaccine is comprised of the Matrix-M™ adjuvant, and antigen (SARS-CoV-2 spike protein).
  - A dose range of 5-25 µg of antigen is under clinical study. The anticipated dose based on clinical data obtained to date is (µg of antigen with (b µg of Matrix-M adjuvant.
  - For planning purposes, (b) (4) µg antigen/dose) has been used and the calculations in this scope of work have been based on this dose.
  - The antigen production is the rate-limiting step in vaccine production. The Matrix-M adjuvant will be available prior to antigen production. Dose production has been calculated based on the availability of antigen. Novavax is planning on a batch-by-batch rapid fill/finish once antigen is manufactured and available.
  - The estimated production schedule based on the (b µg antigen/dose (base case) and (µg antigen /dose (anticipated case) is in the table below:

	Estimated Schedule of Cumulative Doses Manufactured by Month				
Dosage	**Oct 2020**	**Nov 2020**	**Dec 2020**	**Jan 2021**	**Feb 2021**
(b µg/dose (base case)	(b) (4)				
(µg/dose (anticipated case)	(b) (4)		100,000,000*		

*Actual cumulative projected production at (µg/dose is (b) (4) in December 2020. Some doses may be in progress at the end of December 2020.

**Actual cumulative projected production at (b µg/dose is (b) (4) in February 2021.

The scope includes the following activities:

- Manufacturing
  - Manufacturing of 100M doses (at (b µg/dose, (b) (4)) of NVX-CoV-2373 vaccine in 2020 for distribution to the Government upon EUA under section 564 of the Food, Drug, and Cosmetic (FD&C) Act or a biologics licensure granted under Section 351(a) of the Public Health Service Act by the U.S. FDA.
  - Establishment of large-scale current Good Manufacturing Practice (cGMP) manufacturing capacity compliant with 21 CFR Parts 210 and 211, and the DSCA to the extent applicable at the time of manufacturing by statute and FDA interpretive guidance thereof.
  - Comparability among clinical vaccine lots and commercial lots using a comparability protocol linked to the product associated with the Phase 1 clinical study. For adjuvant components, the same raw material lot(s) will be used for the current and new Contract

Manufacturing Organization (CMO) processes for the comparability protocol, and the same test lab will be used to ensure only process differences are being evaluated.

- Validation of manufacturing processes will be performed to cGMP standards.

- Clinical
  - Phase 3 pivotal clinical trial harmonized with USG clinical strategies.
  - A Phase 3 clinical trial in pediatric populations (<18 years).
  - Phase 2 studies in at-risk subpopulations (co-morbidities, (b) (4) immunocompromised), as well as studies to support manufacturing site comparability.

- Non-clinical
  - Studies to support EUA and regulatory approval (BLA).

- Regulatory
  - EUA submission when data supports it, while maintaining progress toward eventual BLA submission.
  - BLA submission when appropriate.
  - Regulatory support activities (Investigational New Drug (IND) submissions) for manufacturing, clinical, non-clinical studies.
  - Meetings as-needed with regulators.

- Project Management
  - Mandatory reporting requirements, as described in the Base Agreement.
  - Submission of Quarterly Progress Reports. Format will be agreed on by the contractor and Agreements Officer's Representative (AOR), and will include both technical and financial status and expenditure forecast.
  - Facilitation of biweekly teleconferences with Novavax and USG Subject Matter Experts.
  - Final prototype project report and applicable patents report(s).
  - Work Breakdown Structure (WBS) and Integrated Master Schedule (IMS).
  - All Regulatory correspondence relevant to the scope of work proposed, including communications with the FDA, and all submissions.

1.4.1 Novavax Project Plan

This is Novavax's plan as of the date of the submission. Novavax desires to move quickly to large scale development as rapidly as possible, in order to meet the objectives of this proposal. As the COVID-19 pandemic is an evolving situation, Novavax may need to adapt its plan in response to FDA guidance, opportunities for manufacturing efficiencies, and clinical trial data.

1.5 Resolution of Conflicting Language

If there is a conflict between the Project Agreement (of which this Statement of Work is part) and the Base Agreement (Medical CBRN Consortium (MCDC) Base Agreement No.: 2020-530), the Project Agreement language will supersede and control the relationship of the parties.

2.0 APPLICABLE REFERENCES

N/A

3.0 REQUIREMENTS

3.1 Major Task: cGMP Manufacturing of NVX-CoV-2373 compliant with 21 CFR 210 and 211

3.1.1 Subtask: Raw Materials – Obtain Critical Starting Materials for Adjuvant Manufacturing

Sufficient Saponin to manufacture up to 100M vaccine doses will be purchased (Desert King, headquartered in San Diego, CA, facilities in Chile). Long-lead, critical, and limited-supply materials (b) (4) will be purchased for the additional 560M vaccine doses to meet the contact requirement, in order to ensure capability to rapidly manufacture to meet surge requirements with little advance notification and demonstrate capability to stockpile and distribute large quantities of the vaccine to respond when needed.

3.1.2 Subtask: Raw Materials – Obtain Critical Starting Materials for Antigen and Fill/Finish Manufacturing

Sufficient materials (vials, stoppers, other consumables) to manufacture up to 100M vaccine doses will be purchased (sources TBD).

3.1.3 Subtask: Raw Materials – (b) (4) Intermediates to Produce Matrix-M Adjuvant Matrix-M Adjuvant

(b) (4) to supply large-scale manufacturing of vaccine doses will be manufactured at (b) (4) and PolyPeptide (Torrance, CA & Malmö, Sweden). Technology transfer and start-up of the PolyPeptide facility in Torrance, CA will be completed. Long lead, critical, and limited supply materials will be purchased in order to achieve the goal of large-scale production.

3.1.4 Subtask: Matrix-M Adjuvant Manufacturing to Supply 100M Vaccine Doses

Matrix-M Adjuvant bulk components will be manufactured at ACG Biologics (Seattle, WA) to supply 100M vaccine doses. Technology transfer and start-up of the AGC Bio facility in Seattle will be completed. An analytical comparability manufacturing study and validation studies will be performed as part of the tech transfer to each manufacturing site.

3.1.5 Subtask: Antigen Manufacturing to Supply 100M Vaccine Doses

Antigen will be manufactured at Fuji (2 sites – College Station, TX and Research Triangle Park, NC) to supply 100M vaccine doses. Technology transfer and scale-up activities will be completed. An analytical comparability manufacturing study and validation studies will be performed as part of the tech transfer to each manufacturing site.

3.1.6 Subtask: Fill/Finish of 100M Vaccine Doses

100M doses of finished vaccine in (b) (4) vials will be manufactured at Baxter (Bloomington, IN, USA). This will include secondary packaging. Technology transfer and scale-up activities will be completed. An analytical comparability manufacturing study and validation studies will be performed as part of the tech transfer to each manufacturing site.

3.1.7 Subtask: Shipping and Storage

Novavax assumes that it will maintain a Vendor Managed Inventory (VMI) system for a period of 12 months, with shipments to 10 geographic zones in the USA. Novavax will perform activities to establish compliance with DSCA to the extent applicable at the time of manufacturing, by statute and FDA interpretive guidance thereof.

3.2 Major Task: Clinical Studies

Novavax will perform these clinical trials and deliver the results in an interim Clinical Study Report (CSR) at the completion of enrollment, and the final CSR when available. These trials will be conducted using a Clinical Research Organization (CRO) that is to be determined.

3.2.1 Subtask: Phase 3 Global Efficacy Study, Adults ≥ 18 and < 75 years

Study: Phase 3 – Global Efficacy Study (to be harmonized with other USG studies), 2019nCoV-301.

Population: Adults ≥ 18 years, inclusive of subjects with more severe co-morbid conditions.

Locations: North America, Europe; may include Africa, Asia, Oceania, South America.

Primary Objectives: Clinical efficacy, safety, immunogenicity.

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix-M – dose determined by Phase 2 dose confirmation study, Placebo; ~0.5 mL dose Intramuscular (IM) injection, up to 2 doses at Day 0 and Day 21.

Enrollment: TOTAL N: ~30,000 (adjusted for expected endpoint incidence). (b) (4)

3.2.2 Subtask: Phase 2 Efficacy Expansion (US), Adults ≥ 18 and < 75 years

Study: Phase 2 - Part 3 efficacy expansion (US), 2019nCoV-204.

Population: Adults ≥ 18 and < 75 years.

Locations: USA.

Primary Objectives: Clinical efficacy, safety, immunogenicity.

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix-M (b) (4) ; not greater than 25 µg antigen + 50 µg adjuvant, (b) (4) to allow for rapid initiation. Placebo. ~0.5 mL dose IM injection, up to 2 doses at Day 0 and Day 21.

Enrollment: TOTAL: (b) (4) Adjusted for expected event occurrence. Event driven analysis. Initiation of study gated on completion of Phase 1 study, dose-selection and regulatory approval.

3.2.3 Subtask: Phase 2 Study in Immunocompromised Persons (HIV-positive adult subjects) (Africa)

Study: Phase 2 study in immunocompromised persons (HIV-positive adult subjects) (Africa).

Population: Adults ≥ 18 and < 65 years.

Locations: Republic of South Africa (RSA)

Primary Objectives: Safety, immunogenicity (serum and cellular).

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix-M; Placebo, 0.5 mL dose IM injection, up to 2 doses at Day 0 and Day 21.

Enrollment: Total N = 2,640 – 2,880 (with n=240 - 480 HIV+); 1:1 Vaccine to placebo. Initiation gated on completion of Phase 1 study, dose selection, and regulatory approval.

3.2.4 Subtask: (b) (4)

Study: (b) (4)

Population: (b) (4)

Locations: (b) (4) .

Primary Objectives: (b) (4)

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix-M (b) (4)

Enrollment: (b) (4) Initiation gated on benefit:risk assessment (derived from Task 2.3.1 and/or 2.3.2 and/or other Phase 2 studies) and regulatory approval to conduct studies in this vulnerable population.

3.2.5 Subtask: Phase 2 Manufacturing Site Lot Consistency/Comparability Study (US or other)

Study: Phase 2 manufacturing site lot consistency/comparability study (US or other), 2019nCoV-201.

Population: Adults ≥ 18 to < 50 years.

Locations: USA.

Primary Objectives: Safety, immunogenicity.

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix-M; (b) (4) [redacted]

Enrollment: ~600 per cohort, each cohort having 1:1 randomization with Emergent (antigen)/Novavax AB (adjuvant) manufacturing site and new manufacturing sites. Study size may be adjusted to allow non-inferiority testing.

3.2.6 Subtask: (b) (4) [redacted]

Study: (b) (4) [redacted]

Population: (b) (4) [redacted]

Locations: (b) (4) [redacted]

Primary Objectives: (b) (4) [redacted]

Design: Randomized, observer-blinded, placebo-controlled.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix-M; (b) (4) [redacted]

Enrollment: Total = 800 mothers + baby. Initiation gated on benefit:risk assessment (derived from Task 2.3.1 and/or 2.3.2 and/or other Phase 2 studies) and regulatory approval to conduct studies in this vulnerable population.

3.2.7 Subtask: Pharmacovigilance; Establishment of Registration Safety Database

A registration safety database will be established to comply with FDA requirements for product safety and licensure.

3.2.8 Subtask: (b) (4) [redacted]

Study: (b) (4) [redacted]

Population: (b) (4) [redacted]

Location: (b) (4) [redacted]

Primary Objective: (b) (4) [redacted]

Design: Randomized, observer-blinded, placebo (or active vaccine) control.

Test Product(s); Dose Regimen; Route of Administration: Vaccine + Matrix-M (b) (4) [redacted]

Enrollment: TOTAL: N ~12,500 (based on agreed VE, power, and LBCI). (b) (4) [redacted] Adjusted for expected event occurrence if robust demonstration of clinical efficacy is required by the FDA. Event driven analysis for study termination.

3.3 Major Task: Non-Clinical Studies

Novavax will perform these non-clinical studies and deliver the results in a study report at completion.

3.3.1 Mouse Study, Immunogenicity

Study 702-100. Immunogenicity ((b) (4)) in mice for vaccine efficacy profile to comply with FDA guidelines.

3.3.2 Rhesus Study, Immunogenicity

Study 702-099. Immunogenicity/challenge ((b) (4)) in rhesus monkeys for vaccine efficacy profile to comply with FDA guidelines.

3.3.3 Hamster Study, Immunogenicity

Study 702-102. Immunogenicity/challenge study in hamster ((b) (4) [redacted]) for vaccine efficacy profile to comply with FDA guidelines.

3.3.4 Mouse Study, T-Cell Immunogenicity

Study 702-103. T-cell immunogenicity/challenge study in mice ((b) (4) [redacted]) for vaccine efficacy profile to comply with FDA guidelines.

3.3.5 Hamster Study, T-Cell Immunogenicity

Study 702-105. Immunogenicity/challenge study in hamster ((b) (4) [redacted]) for vaccine efficacy profile to comply with FDA guidelines.

3.3.6 Mouse Study, T-Cell Immunogenicity

Study 702-104. Immunogenicity/challenge study in hamster ((b) (4) [redacted] for vaccine efficacy profile to comply with FDA guidelines.

3.3.7 Non-Clinical Studies: Collaboration with Univ. of Maryland School of Medicine

Three studies to study enhancement/inhibition and neutralization, and virus challenge of vaccinated mice:

1. Validation of Spike nanoparticles in cell inhibition studies: In vitro inhibition studies on cell line permissive to r2019-nCoV, readout TBD.
2. Neutralization studies with virus against bleeds from mice, In vitro microneutralization studies on cell line permissive to r2019-nCoV, TCID50 or fluorescence readout (TBD).
3. Virus challenge of vaccinated mice (mice vaccinated outside and shipped to UM for challenge), Challenge of vaccinated mice (shipped in for infection from Novavax), Lung pathology, Titer, viral Ribonucleic Acid (RNA) quantitation, pathology scoring and reports.

3.3.8 Structural Study of COVID-19 Spike Protein and its Complex with Host Receptor (cooperation with Baylor College of Medicine)

Study to determine the structures of recombinant COVID-19. Spike protein in nanoparticles used in Novavax's human vaccine and in complex with its host receptor ACE2. Will obtain a high-resolution cryoEM structure of full-length COVID-19 Spike protein and a high-resolution cryoEM structure of full-length COVID-19 Spike protein in complex with human receptor ACE2.

3.3.9 Neutralizing Assay Histopathology for On-going (b) (4)

Histopathology readings for current neutralization studies in (b) (4). This will support the safety profile of the vaccine for FDA approval.

3.3.10 Mouse Study, Immunogenicity (b) (4) Studies

Individual immunogenicity studies (b) (4)) in mice for vaccine efficacy profile in different sub-populations to comply with FDA guidelines.

3.3.11 Durability of NVX-CoV2373 Vaccine Immunity and SARS-CoV-2 Protection at (b) in Rhesus Macaques

Study 702-110. This study is designed to evaluate the long-term immunogenicity and protective efficacy of NVX-CoV2373 nanoparticle vaccine when administered with Matrix-MTM by IM injections on Study Days 0 and 21, to Non-Human Primates (NHP). Each study group will contain (b) (4) NHPs (b) (4) per sex). Blood samples will be collected prior to vaccination and at multiple time points following vaccination as outlined below. Samples will be shipped to Novavax Inc. for performance of assays to determine the vaccine immunogenicity. Animals from placebo and active treatment groups will be challenged with SARS-CoV-2 virus at (b) (4) following last treatment and monitored for clinical illness, viral RNA and sgRNA (nasal swabs, BAL) to assess the protective efficacy of the vaccine.

3.3.12 Immunogenicity and Protective Efficacy of Sub-Protective Doses of NVX-CoV2373 in Rhesus Macaques

Study 702-111. This study is designed to evaluate the immunogenicity and protective efficacy of sub-optimal doses of NVX-CoV2373 nanoparticle vaccine administered with a fixed dose of Matrix-MTM by IM injections on Study Days 0 and 21, to NHPs. Each study group will contain (b) (4) NHPs (b) (4) per sex). Blood samples will be collected prior to vaccination and at various time points following vaccination as outlined below. Samples will be shipped to Novavax Inc. for performance of assays to determine the vaccine immunogenicity. Animals from placebo and active treatment groups will be challenged with SARS-CoV-2 virus at (b) (4) following last treatment and monitored for clinical illness, viral RNA and sgRNA (nasal swabs, BAL) to assess the protective efficacy of the vaccine.

3.4 Major Task: Regulatory Affairs

Novavax will conduct the regulatory activities below, including BLA prep and submission, and provide the meeting minutes and applications to the USG.

3.4.1 Subtask: EUA Submission and Supporting Meetings and Regulatory Filings

An EUA will be submitted to the FDA upon obtaining sufficient clinical data. EUA, FDA meetings to support EUA, submission planning support for the Chemistry, Manufacturing, and Controls (CMC) team, EUA strategy and meeting support, and submission preparation support activities, will all be completed.

3.4.2 Subtask: IND Submission Updates and FDA Meetings

This task will include submissions to the IND and possible FDA meetings that will be required prior to the BLA submission.

3.4.3 Subtask: BLA Submission

A BLA will be submitted to the FDA upon obtaining sufficient clinical data, FDA meetings to support BLA, submission planning support for the CMC team, BLA strategy and meeting support, and submission preparation support activities, will all be completed.

3.5 Major Task: Project Management and Reporting

3.5.1 Subtask: Kick-Off Meeting and Initial Baseline Review of IMS

Novavax shall conduct a Kick-Off Meeting and an initial review with the USG of the IMS, upon initiation of the program.

3.5.2 Subtask: Biweekly Meetings with OWS

Novavax shall submit the agenda in advance. Any technical updates shall be provided in advance for the Government team to review. Minutes shall be submitted after the biweekly meeting to the USG.

3.5.3 Subtask: Written Quarterly Reports

Novavax shall submit quarterly reports to the USG.

3.5.4 Subtask: Written Annual Reports

Novavax shall submit the annual reports to the USG.

3.5.5 Subtask: Written Final Report

Novavax shall submit the final report to the USG.

3.6 Optional Task: Follow-On Production

Follow-on production of finished doses of vaccine up to 560M doses.

4.0 DELIVERABLES

Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Type/Data Rights
	Manufacturing					
4.1	(b) (4) [redacted]	[redacted]	5.1	3.1.1	Reviewer	(b) (4) [redacted]

Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Type/Data Rights
	(b) (4)					
4.2	(b) (4)	[redacted]	5.2	3.1.2	Reviewer	(b) (4)
4.3	(b) (4)	[redacted]	5.3	3.1.3	Reviewer	(b) (4)
4.4	(b) (4)	[redacted]	5.4	3.1.4	Reviewer	(b) (4)
4.5	(b) (4)	[redacted]	5.5	3.1.5	Reviewer	(b) (4)
4.6	(b) (4)	[redacted]	5.6	3.1.6	Reviewer	(b) (4)
4.7	(b) (4)	[redacted]	5.7	3.1.7	Reviewer	(b) (4)
	Clinical					
4.8	(b) (4)	[redacted]	5.8	3.2.1	Reviewer	(b) (4)
4.9	(b) (4)	[redacted]	5.9	3.2.2	Reviewer	(b) (4)

[1] As used herein, "Government Purpose Rights" has the meaning set forth in Article XI, Section 11.01(9) of the Base Agreement, as modified by Section 8.2(b) below.

Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Type/Data Rights
4.10	(b) (4)		5.10	3.2.3	Reviewer	(b) (4)
4.11	(b) (4)		5.11	3.2.4	Reviewer	(b) (4)
4.12	(b) (4)		5.12	3.2.5	Reviewer	(b) (4)
4.13	(b) (4)		5.13	3.2.6	Reviewer	(b) (4)
4.14	(b) (4)		5.14	3.2.7	Reviewer	(b) (4)
4.15	(b) (4)		5.15	3.2.8	Reviewer	(b) (4)
	Non- Clinical					
4.16	(b) (4)		5.16	3.3.1	Reviewer	(b) (4)
4.17	(b) (4)		5.17	3.3.2	Reviewer	(b) (4)
4.18	(b) (4)		5.18	3.3.3	Reviewer	(b) (4)
4.19	(b) (4)		5.19	3.3.4	Reviewer	(b) (4)
4.20	(b) (4)		5.20	3.3.5	Reviewer	(b) (4)

Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Type/Data Rights
	(b) (4)					
4.21	(b) (4)	[redacted]	5.21	3.3.6	Reviewer	(b) (4)
4.22	(b) (4)	[redacted]	5.22	3.3.7	Reviewer	(b) (4)
4.23	(b) (4)	[redacted]	5.23	3.3.8	Reviewer	(b) (4)
4.24	(b) (4)	[redacted]	5.24	3.3.9	Reviewer	(b) (4)
4.25	(b) (4)	[redacted]	5.25	3.3.10	Reviewer	(b) (4)
4.26	(b) (4)	[redacted]	5.26	3.3.11	Reviewer	(b) (4)
4.27	(b) (4)	[redacted]	5.27	3.3.12	Reviewer	(b) (4)
	Regulatory Affairs					

Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Type/Data Rights
4.28	(b) (4)		5.28	3.4.1	Reviewer	(b) (4)
4.29	(b) (4)		5.29	3.4.2	Reviewer	(b) (4)
4.30	(b) (4)		5.30	3.4.3	Reviewer	(b) (4)
	Project Management					
4.31	(b) (4)		5.31	3.5	Reviewer	(b) (4)
4.32	(b) (4)		5.32	3.5.1	Reviewer	(b) (4)
4.33	(b) (4)		5.33	3.5.2	Reviewer	(b) (4)
4.34	(b) (4)		5.34	3.5.3	Reviewer	(b) (4)
4.35	(b) (4)		5.35	3.5.4	Reviewer	(b) (4)
4.36	(b) (4)		5.36	3.5.4	Reviewer	(b) (4)
4.37	(b) (4)		5.37	3.5.5	Reviewer	(b) (4)

Del. #	Deliverable Description	Due Date	Milestone Reference	SOW Reference	Government Role	Data Type/Data Rights
4.38	(b) (4)		5.35	N/A	Reviewer	(b) (4)
TBD	(b) (4)		Option 1	3.6	Reviewer	(b) (4)

Note: Attachment D of the Project Agreement shall be referenced for supplemental security requirements associated with deliverables under this project.

5.0 MILESTONE PAYMENT SCHEDULE

The milestones below are for reference and costs for the project will be invoiced monthly on a time and materials basis as the work progresses.

Milestone #	Milestone Description (Deliverable Reference)	Due Date	Total Program Funds
	Manufacturing		(b) (4)
5.1	(b) (4)		
5.2	(b) (4)		
5.3	(b) (4)		
5.4	(b) (4)		
5.5	(b) (4)		
5.6	(b) (4)		
5.7	(b) (4)		
	Clinical		(b) (4)
5.8	(b) (4)		
5.9	(b) (4)		
5.10	(b) (4)		
5.11	(b) (4)		
5.12	(b) (4)		
5.13	(b) (4)		

Milestone #	Milestone Description (Deliverable Reference)	Due Date	Total Program Funds
5.14	(b) (4)		
5.15	(b) (4)		
	Non- Clinical		(b) (4)
5.16	(b) (4)		
5.17	(b) (4)		
5.18	(b) (4)		
5.19	(b) (4)		
5.20	(b) (4)		
5.21	(b) (4)		
5.22	(b) (4)		
5.23	(b) (4)		
5.24	(b) (4)		
5.25	(b) (4)		
5.26	(b) (4)		
5.27	(b) (4)		
	Regulatory Affairs		(b) (4)
5.28	(b) (4)		
5.29	(b) (4)		
5.30	(b) (4)		
	Project Management		(b) (4)
5.31	(b) (4)		
5.32	(b) (4)		
5.33	(b) (4)		

Milestone #	Milestone Description (Deliverable Reference)	Due Date	Total Program Funds
		(b) (4)	
5.34	(b) (4)		
5.35	(b) (4)		
5.36	(b) (4)		
5.37	(b) (4)		
5.38	(b) (4)		
	Reservation Fees		
5.39	(b) (4)		
5.40	(b) (4)		
5.41	(b) (4)		
	Total (Cost Plus Fixed Fee)		**$1,747,689,328**
	Period of Performance (July 6, 2020 – December 31, 2021)		**18 Months (Base)**
	Option 1: Follow-On Production		**Cost:** (b) (4)

6.0 SHIPPING PROVISIONS

The shipment of physical deliverables shall be coordinated with the AOR. Data deliverables shall be provided in accordance with the agreement, and in coordination with the AOR.

7.0 INTELLECTUAL PROPERTY, DATA RIGHTS, AND COPYRIGHTS

7.1 BACKGROUND IP

(a) Ownership. Prior to June 8, 2020, Novavax had funded the development of NVX-CoV2373, and other antecedent vaccine programs relevant to Novavax' proprietary position in the development of NVX-CoV2373, as well as its sf9/baculovirus manufacturing platform, (all "Background IP") through private funding or in collaboration with a funding partner other than the U.S. Government. Such private and non-governmental funding has continued since June 8, 2020 and is expected to continue during the performance of the Project Agreement. A list of all patents and patent applications included in the Background IP is provided below as Enclosure 4. Background IP also consists of (a) manufacturing know-how, including, without limitation, the NVAX-Cov2373 manufacturing process definitions, process development/characterization reports, laboratory scale process procedures, manufacturing records, analytical test methods, product quality target ranges/specifications, quality target product profile, critical quality attributes

(collectively "Background Know-How"), (b) data from pre-clinical and clinical research studies, analytical and process development research, and data related to, or generated using, the Background Know-How (collectively, "Background Data"), and (c) proprietary manufacturing materials, including, without limitation, sf9 cell banks (master and working), baculovirus virus stock (master and working), product standards, reference standards, and critical reagents ("Background Materials"). On June 8, 2020, Novavax and the U.S. Department of Defense entered into a Letter Contract for specified U.S.-based clinical and manufacturing development of NVX-CoV2373 which acknowledged Background IP and made no explicit U.S. Government claims to Background IP or subsequent data arising therefrom. The U.S. Government hereby acknowledges such Background IP in full and further acknowledges that it has no ownership rights to Novavax Background IP under this Project Agreement.

(b) Background IP Limited License to Government. Subject to the terms of the Project Agreement, Novavax grants the U.S. Government a nonexclusive, worldwide, nontransferable, non-sublicenseable license to use the Background IP to the limited extent necessary for the U.S. Government to review and use the Deliverables tendered by Novavax under this Agreement identified in Section 4.0 above, and for no other purpose; provided that the U.S. Government agrees that it may not disclose the Background IP to third parties, or allow third parties to have access to, use, practice or have practiced the Background IP, without Novavax's prior written consent. To the extent that a Deliverable with Foreground IP incorporates or uses Background IP, the Deliverable shall be deemed and considered to comprise Background IP and shall be used by the U.S. Government in accordance with this Background IP Limited License.

(c) Background IP License to Novavax. Subject to the terms of the Project Agreement, the U.S. Government grants to Novavax a nonexclusive, worldwide, nontransferable, irrevocable, paid-up license to any intellectual property (including patents and patent applications) to which the U.S. Government has rights thereto, provided that such license is limited to such intellectual property rights necessary to perform Novavax's obligations under the Project Agreement.

7.2 FOREGROUND IP

(a) Ownership. Notwithstanding anything in the Base Agreement to the contrary, Novavax owns all rights, title and interest in and to any development, modification, discovery, invention or improvement, whether or not patentable, conceived, made, reduced to practice, or created in connection with activities funded under the Project Agreement, including, without limitation, all data and inventions, and intellectual property rights in any of the foregoing ("Foreground IP").

(b) Foreground IP Special License. Subject to the terms of the Project Agreement, Novavax grants the U.S. Government a nonexclusive, worldwide, nontransferable, irrevocable, paid-up license to practice or have practiced the Foreground IP for or on behalf of the U.S. Government ("Foreground IP Special License").

8.0 DATA RIGHTS

Article XI, §11.03 of the Base Agreement is hereby amended, consistent with the "Specifically Negotiated License Rights" capability at Article XI, §§11.01(12) and 11.03(4), as follows:

8.1 Data Ownership.

Novavax owns all rights, title and interest to all Data (as defined in Article XI, Section 11.01(7) of the Base Agreement) generated as a result of the work performed under this Project Agreement, including Subject Data.

8.2 Rights to Data.

(a) Subject Data. Subject to the terms of the Project Agreement, Novavax grants to the U.S. Government a Government purpose rights license to Subject Data that will convert to an unlimited rights license (as the term is defined in Article XI, Section 11.01(14) of the Base Agreement)[2] after three (3) years from the date of delivery. As used herein, "Subject Data" shall mean Technical Data under Article XI, §11.01(13) of the Base Agreement Deliverables that are considered Subject Data are identified in the Deliverable Table set forth in Section 4.0 above.

(b) Transfer of Data. Each party, upon written request to the other party, shall have the right to review and to request delivery of Subject Data, and delivery of such Data shall be made to the requesting party within two weeks of the request, except to the extent that such Data are subject to a claim of confidentiality or privilege by a third party.

(c) Background IP Limited License. To the extent that Subject Data incorporates or uses Background IP, the data shall be deemed and considered to comprise Background IP and shall be used by the U.S. Government in accordance with the Background IP Limited License set forth in Section 7.3 above.

8.3 Background Technical Data Rights Assertions.

Novavax asserts background technical data rights as follows:

The Background Data, as defined in Section 7.1 above, was developed through private funding or in collaboration with a funding partner other than the U.S. Government. Such funding is expected to continue; accordingly, Novavax asserts Background Data as Category A Data pursuant to section 11.02(1) of the Base Agreement and the U.S. Government shall have no rights therein.

9.0 REGULATORY RIGHTS

This agreement includes research with an investigational drug, biologic or medical device that is regulated by the U.S. Food and Drug Administration (FDA) and requires FDA pre-market approval or clearance before commercial marketing may begin. It is expected that this agreement will result in the FDA authorization, clearance and commercialization of NVX-CoV-2373 as a Vaccine for

[2] As used herein, "Government Use" as used "Purpose Rights" has the meaning set forth in this Section 4.0 means Government purpose rights as defined in the Base Agreement, Article XI, Section 11.01(9).) of the Base Agreement, as modified by Section 8.2(b) below.

SARS-CoV-2 Coronavirus (the "Technology"). Novavax is the Sponsor of the Regulatory Application (an investigational new drug application (IND), investigational device exemption (IDE), emergency use authorization (EUA), new drug application (NDA), biologics license application (BLA), premarket approval application (PMA), or 510(k) pre-market notification filing (510(k)) or another regulatory filing submitted to the FDA) that controls research under this contract. As the Sponsor of the Regulatory Application to the FDA (as the terms "sponsor" and "applicant" are defined or used in at 21 CFR §§3.2(c), 312.5, 600.3(t), 812.2(b), 812 Subpart C, or 814.20), Novavax has certain standing before the FDA that entitles it to exclusive communications related to the Regulatory Application. This clause protects the return on research and development investment made by the U.S. Government in the event of certain regulatory product development failures related to the Technology.

Novavax agrees to the following:

a. Communications. Novavax will provide the U.S. Government with all communications and summaries thereof, both formal and informal, to or from FDA regarding the Technology and ensure that the U.S. Government representatives are invited to participate in any formal or informal Sponsor meetings with FDA;

b. Rights of Reference. The U.S. Government is hereby granted a right of reference as that term is defined in 21 C.F.R. § 314.3(b) (or any successor rule or analogous applicable law recognized outside of the U.S.) to any Regulatory Application submitted in support of the statement of work for the Project Agreement. When it desires to exercise this right, the U.S. Government agrees to notify Novavax in writing describing the request along with sufficient details for Novavax to generate a letter of cross-reference for the U.S. Government to file with the appropriate FDA office. The U.S. Government agrees that such letters of cross-reference may contain reporting requirements to enable Novavax to comply with its own pharmacovigilance reporting obligations to the FDA and other regulatory agencies. Nothing in this paragraph reduces the U.S. Government's data rights as articulated in other provisions of the Project Agreement.

c. DoD Medical Product Priority. PL-115-92 allows the DoD to request, and FDA to provide, assistance to expedite development and the FDA's review of products to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing American military personnel. Novavax recognizes that only the DoD can utilize PL 115-92. As such, Novavax will work proactively with the DoD to leverage this this law to its maximal potential under this Project Agreement. Novavax shall submit a mutually agreed upon Public Law 115-92 Sponsor Authorization Letter to the U.S. Government within 30 days of award.

10.0 ENSURING SUFFICIENT SUPPLY OF THE PRODUCT

a. In recognition of the Government's significant funding for the development and manufacturing of the product in this Project Agreement and the Government's need to provide sufficient quantities of a safe and effective COVID-19 vaccine to protect the United States population, the Government shall have the remedy described in this section to ensure sufficient supply of the product to meet the needs of the public health or national security. This remedy is not available to the Government unless and until both of the following conditions are met:

i. Novavax gives written notice, required to be submitted to the Government no later than 15 business days, of:

a. any formal management decision to terminate manufacturing of the NVX-CoV-2373 vaccine prior to delivery of 100 million doses to USG;
b. any formal management decision to discontinue sale of the NVX-CoV-2373 vaccine to the Government prior to delivery of 100 million doses to USG; or

c. any filing that anticipates Federal bankruptcy protection; and

ii. Novavax has submitted an Emergency Use Authorization under §564 of the FD&C Act or a biologics license application provisions of §351(a) of the Public Health Service Act (PHSA).

b. If both conditions listed in section (a) occur, Novavax, upon the request of the Government, shall provide the following items necessary for the Government to pursue manufacturing of the NVX-CoV-2373 vaccine with a third party for exclusive sale to the U.S. Government:

i. a writing evidencing a non-exclusive, nontransferable, irrevocable (except for cause), royalty-free paid-up license to practice or have practiced for or on behalf of the U.S. Government any Background IP as defined in clause 7.1 necessary to manufacture or have manufactured the NVX-CoV2373 vaccine;

ii. necessary FDA regulatory filings or authorizations owned or controlled by Novavax related to NVX-Cov2373 and any confirmatory instrument pertaining thereto; and

iii. any outstanding Deliverables contemplated or materials purchased under this Project Agreement.

c. This Article shall be incorporated into any contract for follow-on activities for the Government to acquire and use additional doses of the product. Per section 1.3, the estimated quantity for follow-on production/procurement is approximately 560 million doses.

d. This Article will survive the acquisition or merger of the Contractor by or with a third party. This Article will survive the expiration of this agreement.

11. SECURITY

The security classification level for this effort is UNCLASSIFIED. ***Attachment D of the Project Agreement shall be referenced for supplemental security requirements associated with the execution of this project.***

12.0 MISCELLANEOUS REQUIREMENTS (SAFETY, ENVIRONMENTAL, ETC.)

N/A

13.0 GOVERNMENT FURNISHED PROPERTY/MATERIAL/INFORMATION

14.0 AGREEMENTS OFFICER'S REPRESENTATIVE (AOR) AND ALTERNATE AOR CONTACT INFORMATION

AOR

NAME: (b) (6)
EMAIL: (b) (6)
PHONE: (b) (6)
AGENCY NAME/DIVISION/SECTION: Joint Program Executive Office, Joint Program Lead-Enabling Biotechnologies

Alternate AOR

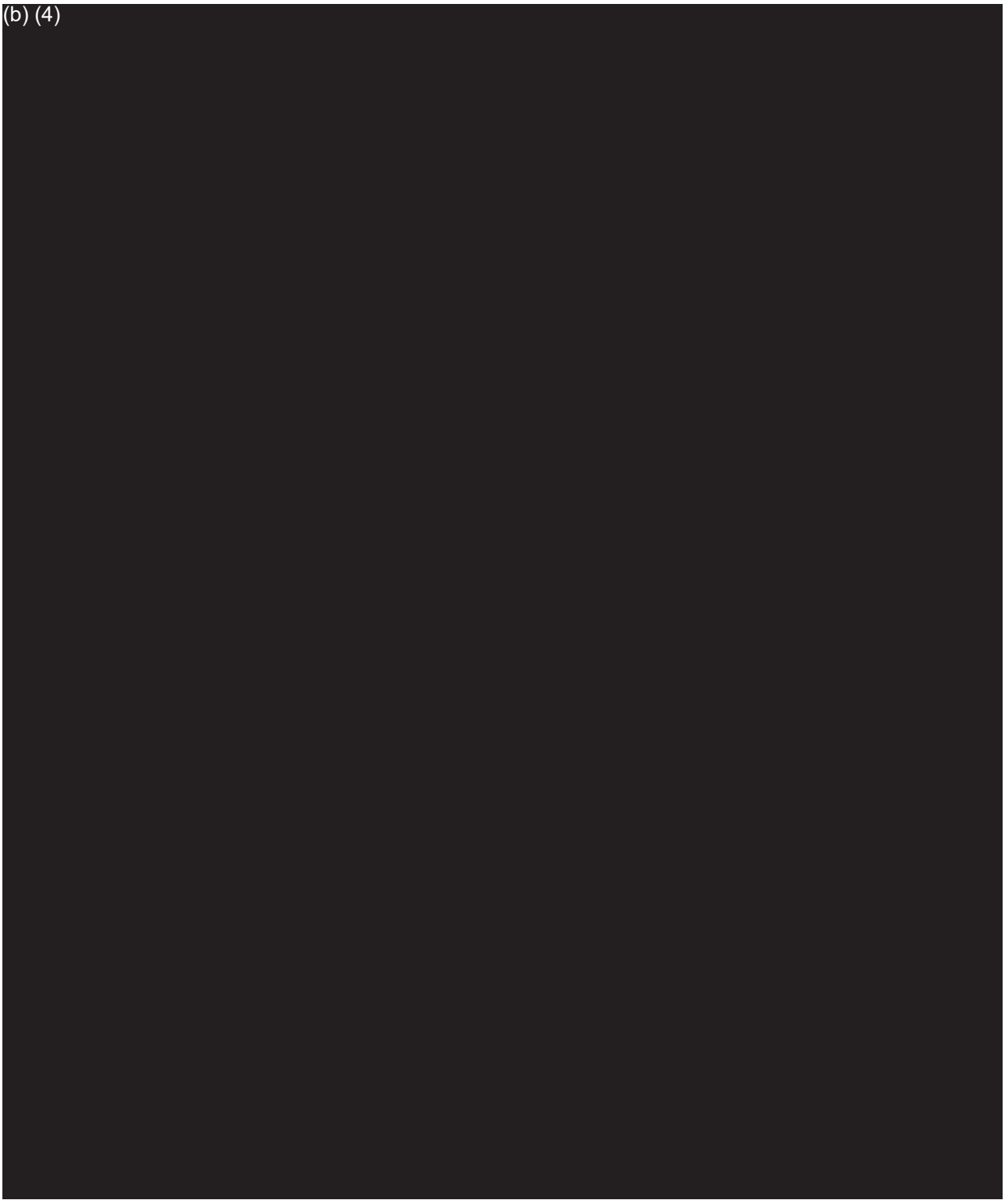
NAME: TBD
MAILING ADDRESS:
EMAIL:
PHONE:
AGENCY NAME/DIVISION/SECTION: HHS/ASPR/BARDA

ENCLOSURE 3: (SUPERSEDED)

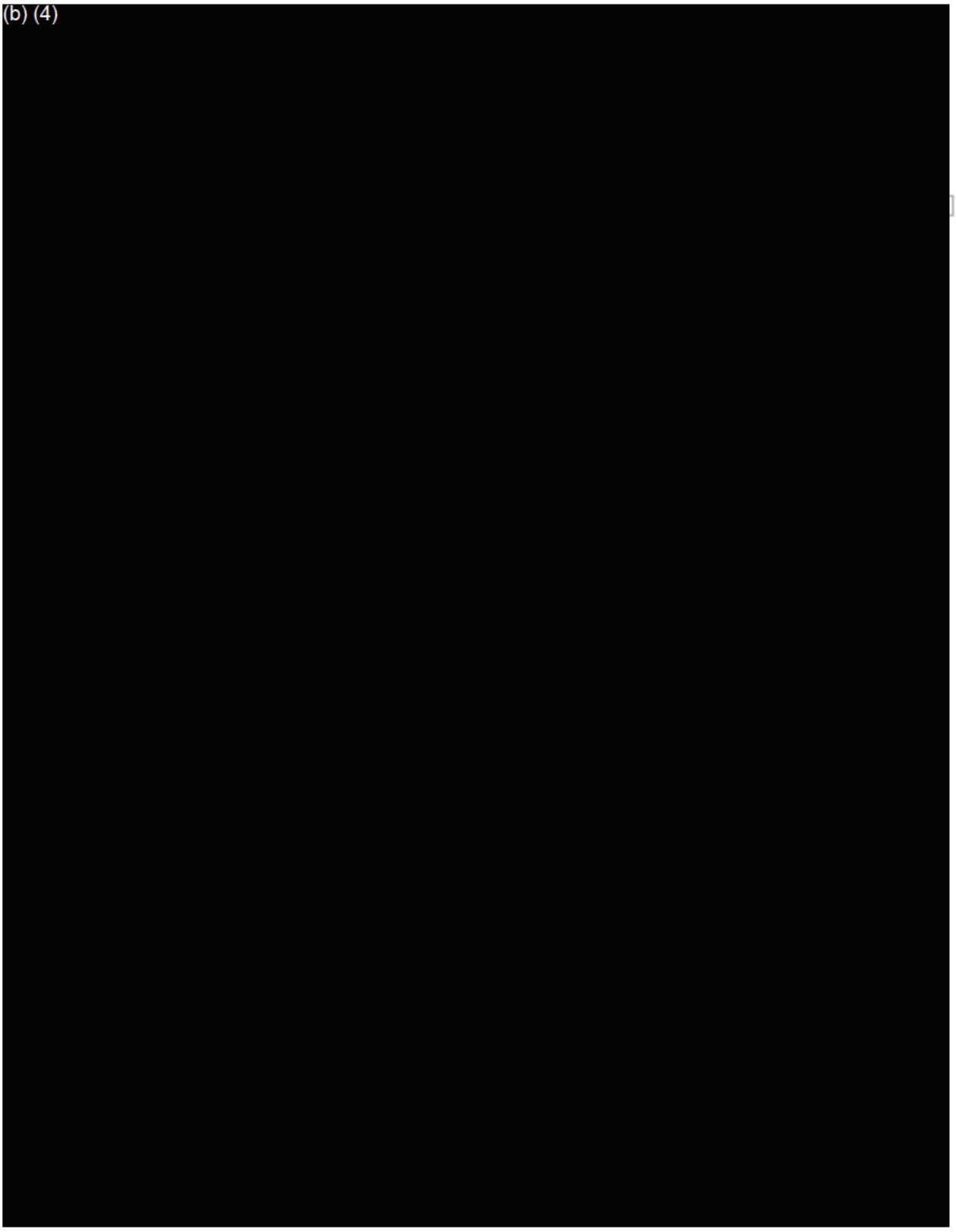
N/A – this enclosure has been superseded from the original and is no longer applicable.

ENCLOSURE 4: PATENT LISTING

(b) (4)



(b) (4)



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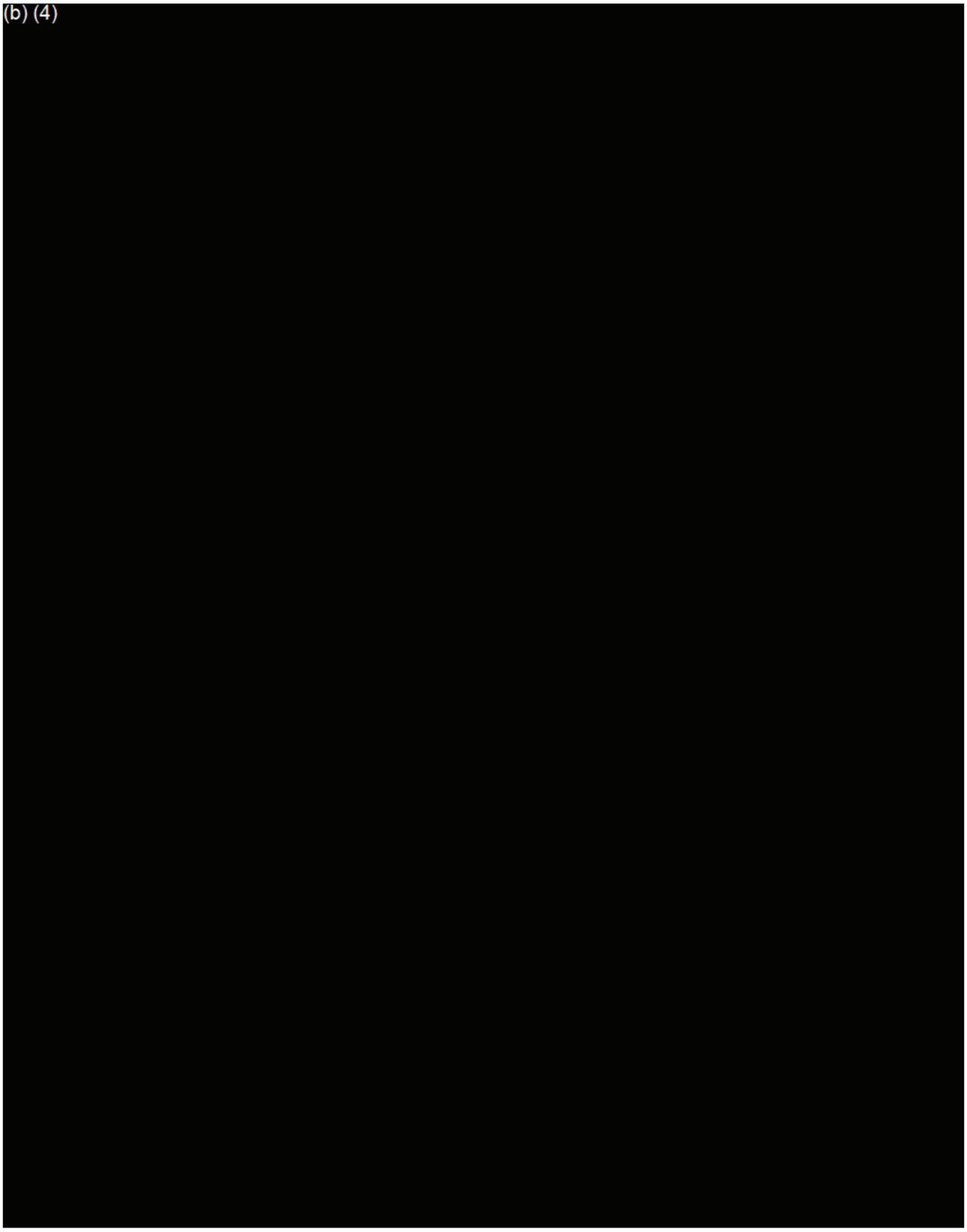

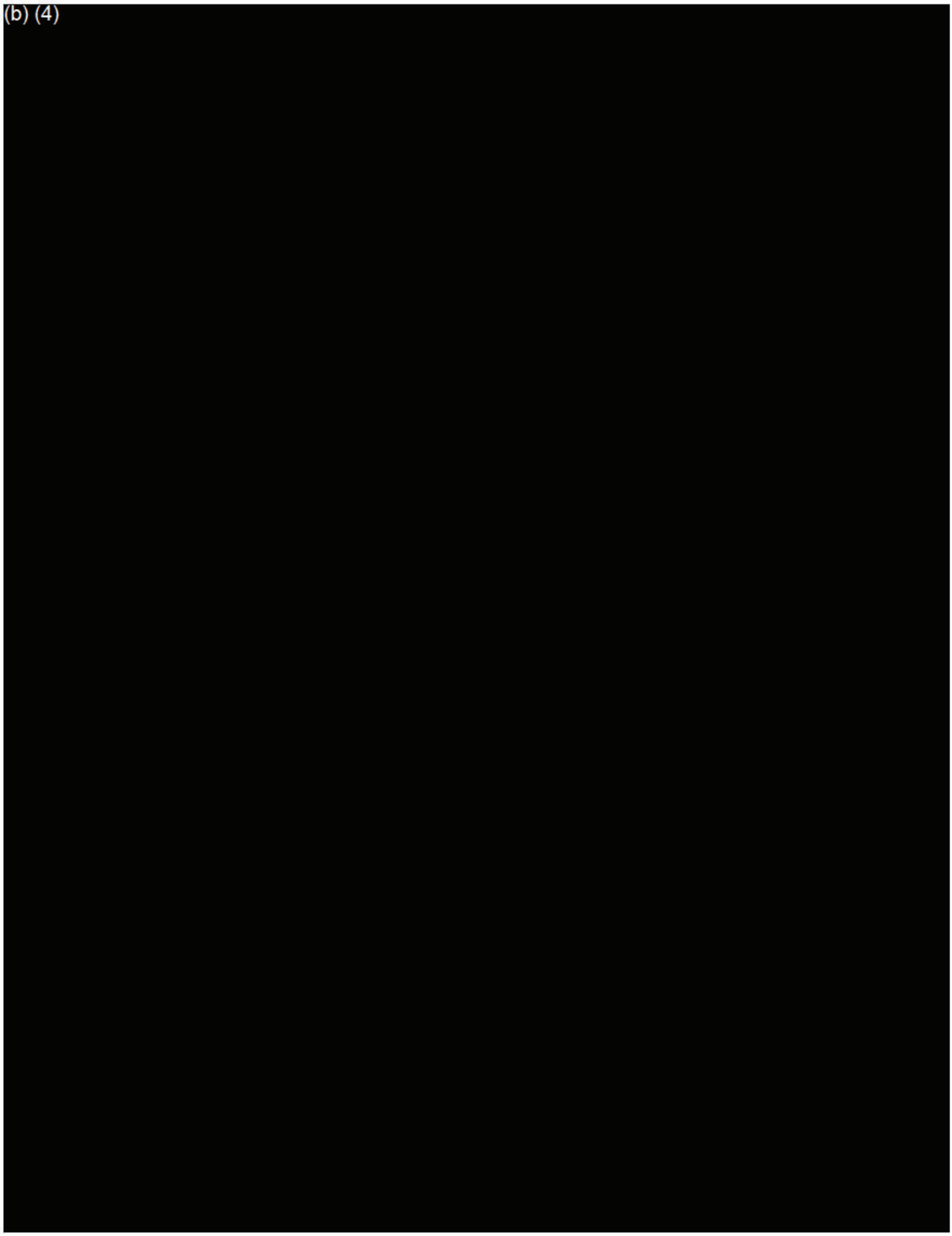

(b) (4)

[redacted]

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